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December 27, 2004

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 2004D-0343

Dear Sir/Madam:

The American Health Care Association (AHCA) is pleased to have the opportunity to provide comments on the Food and Drug Administration (FDA) draft guidance for **Hospital Bed System Dimensional Guidance to Reduce Entrapment** for manufacturers of hospital beds and hospital bed accessories.

AHCA has been a member of the Hospital Bed Safety Workgroup since the FDA convened it in 1999. We appreciate the FDA's concerns about bed safety and its leadership in pursuing improvements to hospital bed safety.

Our comments correspond to the series of requests for comment in the draft guidance.

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Request for Comments: 1. Exclusions (framed flotation therapy products and bed systems using powered air mattress replacements)
Should FDA reconsider these exclusions and recommend the application of dimensional limits for all entrapment areas to these products?

These products provide significant clinical benefits to patients in long term care settings and removal of the exclusion merits serious additional discussion. Many factors should be examined. For example, if the FDA decides to lift the exclusion, would it limit the availability of the equipment to providers? If the exclusion is not changed, would it increase liability of the users of these products? AHCA recommends that, if a decision is made to retain the exclusions, the FDA should make note in the final guidance and other documents related to entrapment that 1) Exclusion from the list does not necessarily mean that the product is free of risk; and 2) Caution is advised to identify and address areas of potential entrapment for each patient. This note should apply to framed flotation therapy products, powered air mattress replacements, and mattress overlays.

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Request for Comments 2 and 3: More stringent dimensional limit at Zone 2 and Zone 3: Should FDA modify its recommendation to recommend a dimensional limit of less than 2 1/3 inches (318mm)?

Yes, the limits should be increased based on FDA's data. Our understanding is that these two zones are in the group identified as posing the greatest potential risk. The care provided to patients in these beds would not be affected by a change in the dimensional limit and the level of risk would be reduced.

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Request for Comments 4, 5, and 6: Recommendations for a dimensional limit for Zones 5, 6 and 7. Should FDA recommend dimensional limits for these additional zones as specified at each respective section in the guidance?

Yes. However, FDA should consider making additional dimensional limit recommendations for zones 5-7 in a second phase of guidance. We recommend focusing first on zones 1-4, which are the zones that are more frequently identified in entrapment reports to the FDA. If the FDA directs manufacturers to focus design changes on all zones simultaneously, this action may reduce the timeliness and effectiveness of the design changes that are intended to reduce potential entrapments at zones 1-4.

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Additional Request for Comments 7: Articulated bed positions. Should FDA apply these dimensional limits to articulated positions?

Yes. As FDA states in the description of zones 1-6, articulation alters the size of the entrapment zones. In hospitals and nursing homes, hospital beds are used more frequently in articulated positions, usually in the semi-fowlers position, than in the flat deck position. The omission of guidance for manufacturers to addresses the risk of potential entrapment zones on beds in articulated positions would place an unreasonable burden on caregivers to prevent entrapment when a bed is articulated for patient comfort or when clinical factors make articulation of the bed necessary. For example, a patient with dysphagia (difficulty swallowing) must be placed in a semi-sitting position during and immediately after eating to avoid aspiration of food or liquids into the lungs. A patient with certain venous disorders must have legs elevated while in bed. Bed design should not place caregivers in the position of having to choose between the risk of entrapment and the risk of not addressing the patient's clinical needs, which would result in noncompliance with Medicare and Medicaid certification requirements.

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Request for Comments 8: Application of this guidance to all health care settings. Is there a reason why this guidance document should not apply to hospital beds used in all care settings?

No. Entrapment potential is determined by characteristics of the individual patient and a particular bed, not the location of the bed. For example, as FDA states in the guidance introductory statements on page 3, "The populations most vulnerable to

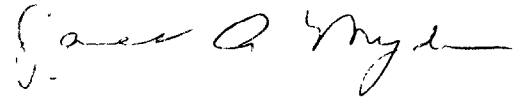
entrapment are elderly patients and residents, especially those who are frail, confused, restless, or who have uncontrolled body movement. Entrapments have occurred in all patient care settings, including hospitals, nursing homes, and private homes."

It is not clear whether FDA intends to apply these guidelines only to newly manufactured beds or also to "legacy" equipment in current use. If the guidance will be applied to all legacy equipment, it would suggest a mandate imposed on healthcare providers, which is not in the agency's purview.

We agree that the guidance could be useful in a variety of healthcare settings, such as hospitals and nursing homes, for assessing and addressing potential entrapment risks of legacy bed systems. We note that the FDA encourages healthcare facilities to contact their equipment suppliers to obtain mitigating solutions to entrapment that are currently on the market. We also acknowledge and agree that the guidance could help healthcare facilities in evaluating and making decisions about the purchase of new bed systems. Facilities' efforts would be enhanced by the availability of additional Hospital Bed Safety Workgroup products such as procedures for the measurement and assessment of hospital bed systems and "A Guide for Modifying Bed Systems and the Use of Accessories to Reduce the Risk of Entrapment."

According to the background section to the draft dimensional guidance, the FDA plans to finalize these products upon publication of the final version of the guidance. We believe that it is important for healthcare providers to be aware of these HBSW products and also to have access to them in order to assess accurately, address entrapment risks and make informed decisions about the effectiveness of existing and future mitigating strategies and solutions. Therefore, the AHCA urges the FDA to assure that the Guide for Modifying Bed Systems and procedures for measurement and assessment are completed and available before proceeding with and recommending that healthcare providers and caregivers apply the final dimensional guidance to their entrapment assessment and reduction efforts.

Sincerely,



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cc: Hal Daub
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